

The QSI System for FDA Document Control provides all the templates and examples needed to complete a well-structured Quality Manual and to create Procedures, Work Instructions, Specifications, Quality Plans and Process Description documents. Features include multi-level access security, FDA compliant electronic signatures, revision control and automated document status updates. Document review and approval workflow across the network can be either sequential or parallel. Activities associated with every document are automatically recorded in the history section. Document archiving of approved documents is automatic and an optional Draft Documents database automatically provides an audit trail that documents time-sequenced development and modification of documents.

OPERATIONAL CONTROLS

For maximum efficiency QSI software provides controls for every aspect of the operation, including: FDA compliant electronic signatures with up to two back-up approver selections for each approver, customer definable numbering options, automated alpha or numeric choices for versioning, user definable text headers for all documents, document review and audit scheduling, automated status tracking of each document, and templates for Procedures, Work Instructions, Process Descriptions, Specifications and Quality Plans.

PROCESS CONTROLS

Beyond operational controls, controls are in place to monitor the process of tasks. Back-up approvers receive automatic notification when documents are not approved by primary approvers within user definable time periods. Missed deadlines for document approvals, document change requests and document audits can be escalated to up to three levels of management. There are automatic electronic notifications and distribution of documents upon approval. The controls enforce predefined document audits with automatic notification to document owners of impending audit dates. There is user definable release scheduling of approved documents to allow for training and the automatic updating of training records prior to document release. For multi-site installations, duplicate document numbering alerts are sent. To ensure accuracy, final approval messages are sent with "comments"

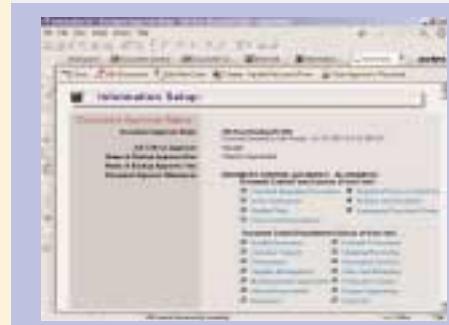
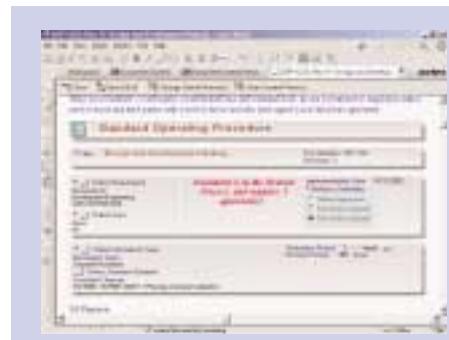
capability and there is an option to notify associated (linked) document owners of changes or new releases. The system allows users to display all documents associated with each individual document for easy access and management.

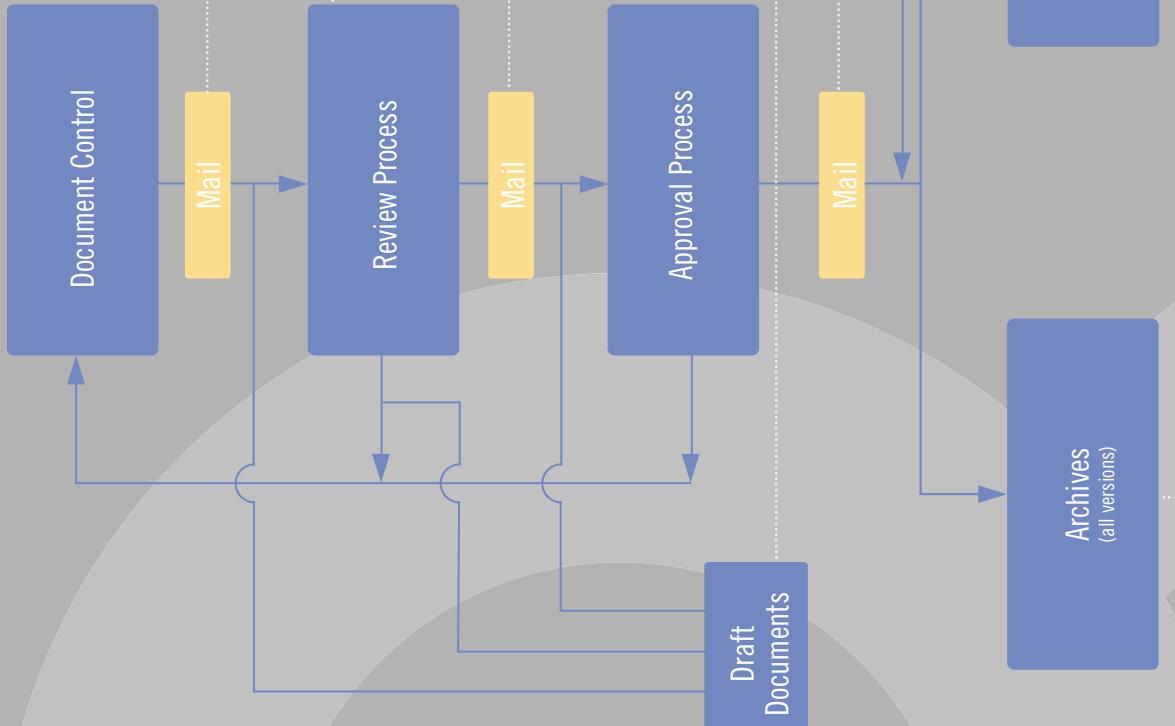
SECURITY CONTROLS

These controls provide selectable approver allowances with 7 levels of database security. Process security prevents documents from being modified in the final approval process. There is selective read access restriction on a per document basis, and if a document is edited, there is an automatic status change alert. The use of dual passwords is required for all document reviewers and approvers. Electronic signatures automatically record date, time and time zone. Password sizes and timeouts are selectable by the system Password Administrator.

PROCESS WORKFLOW

There is a choice of two approval processes, review and final approval. With this flexible workflow, serial or parallel approval is selectable for each document. Upon final approval documents automatically move and replace earlier versions in the Released Documents database. Every released document is automatically archived and stored. Users can define the release dates for approved documents to allow for training.





DOCUMENT CONTROL Create new documents or modify existing ones. Select: document type, numbering system, audit period, release schedule, serial or parallel workflow, send for review or final approval, approver allowances, standard or customer specific form layouts.

MAIL When a document is sent for review all reviewers are automatically notified and a copy of the document is copied into the Draft Documents database.

REVIEW PROCESS An optional review process allows reviewers to approve documents or disapprove with recommendations. A signature countdown is maintained, messages are automatically sent to reviewers and authors for each approval or disapproval and reviewers' comments are recorded in the Draft Documents database.

MAIL When a document is sent for final approval, all approvers are automatically notified and a copy of the document is copied into the Draft Documents database.

APPROVAL PROCESS During the approval process documents cannot be edited, but may be approved or disapproved with comments to the author. Document status is automatically tracked and a signature countdown is maintained.

DRAFT DOCUMENTS Automatically provides an audit trail that documents time-sequenced development and modification of documents.

MAIL Once approved all members of the distribution list are automatically notified.

APPROVED-UNRELEASED DOCUMENTS A holding area is provided for documents with a delayed release date to allow for document training prior to release. Automatic messages are sent to employees to notify them that new documents are available for training.

RELEASED DOCUMENTS The latest approved and released versions automatically replace the previous versions.

DOCUMENT ARCHIVES Contains copies of all approved and released versions of all documents.